REMARKS

The issues in this case are the following:

- Claims 1, 3-7 and 9-22 have been rejected under 35 U.S.C. § 112, first paragraph;
- Claims 1, 3-7 and 9-22 have been rejected under 35 U.S.C. § 112, second paragraph;
- Claims 1, 3-7, 9-22 and 25 have been rejected under 35 U.S.C. § 103(a).

Applicant respectfully requests reconsideration and withdrawal of the foregoing rejections in view of the amendments and remarks herein.

35 U.S.C. § 112, First Paragraph

Claims 1, 3-7, 9-22 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly introducing new matter. Applicant has amended claim 1 to remove the reference to hydroxyl groups *on silica*. Accordingly, reconsideration and withdrawal of this rejection is considered proper and is respectfully requested.

35 U.S.C. § 112, Second Paragraph

Claims 1, 3-7, 9-22 have been rejected under 35 U.S.C. § 112, second paragraph, for use of the phrase "essentially consisting of the steps." Applicant has amended claim 1 to remove the word "essentially." Accordingly, reconsideration and withdrawal of this rejection is considered proper and is respectfully requested.

35 U.S.C. 103(a)

As understood by Applicant, claims 1, 3-7, 9-22 and 25 appear to have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,234,809 to Boom, *et al.* ("Boom") in view of U.S. Patent 6,274,387 to Yamauchi, *et al.* ("Yamauchi").[1] In support of the rejection, the Office Action alleges that Boom discloses all of the limitations of the claims with the exception of the specific dimensions of the particulat carrier. The Office Action then cites Yamauchi as disclosing particles with dimensions whose ranges overlap the ranges recited in the

[1] At page 4 of the Office Action, the rejection is set forth in terms of a one-reference 103 rejection over Boom. However, at page 5 of the Office Action, it is admitted that Boom does not teach the particular carrier dimensions recited in the claims. Yamauchi is then cited for the proposition that the recited dimensions would have been obvious.

claims. The Office Action concludes that it would have been obvious to combine the method of Boom with the nucleic acid binding particulate carrier dimensions taught by Yamauchi because Yamauchi teaches that "the particulate carrier shape and stability with the specified dimensions provide higher dispersibility in a sample -containing solution to maintain dispersion with stirring, with less sedimentation tendency and ready separation. The Office Action also notes that Yamauch teaches that the shape and stability of the particulate silica carrier provides higher absorption capacity, higher adsorption speed and higher reaction efficiency in adsorption and extraction.

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof in view of the following. Applicant respectfully submits that a person of ordinary skill in the art would not have combined the teachings of Boom and Yamauchi to result in the claimed invention.

The present invention specifically requires that the silica particulate carrier bind the nucleic acids "via hydrogen bonds formed between hydroxyl groups **on** the particulate carrier surfaces (claim 1), or that the nucleic acids bind **to the silica** of the particulate carrier (claim 25). By contrast, the entire disclosure of Yamauchi, indeed the *invention* of Yamauchi (especially including the advantages relied upon by the examiner for motivation to combine), is directed toward the use of polyacrylamide coupling agent, coating the entire surface of the particulate carrier, to bind the nucleic acids.

Specifically, the magnetic particles of Yamauchi adsorb and collect nucleic acids by the interaction between nucleic acids and the polyacrylamide chains bonded to the surfaces of magnetic silica:

> **"The magnetic carrier of the invention has polyacrylamide in the surface, so that the polar functional groups such as an amide group capable of interacting with a nucleic acid are fixed not only on the surface of the carrier, but extend as high molecular polyacrylamide chains apart from the surface of the carrier with the end of the polyacrylamide molecule bonded to the carrier surface. Therefore, the active sites of interaction with the high molecular nucleic acid is**

> **increased, and the once formed interaction is firmly held by superposition with polyacrylamide.**" (column 11, line 62 to column 12, line 5)
>
> "**In this range of the nitrogen atom content, the surface of the magnetic carrier is covered almost entirely with polyacrylamide to give stable performance including the adsorption capacity.**" (column 7, lines 2 to 5)

Moroever, the disclosure of Yamauchi makes clear that the polyacrylamide coupling agent is bonded not only to the outer surface, but also to the pore surfaces of the silica magnetic particles of Yamauchi:

> "**The particulate magnetic silica has at least polyacrylamide bonded on the surface thereof.**' (column 5, lines 15 to 16)
>
> "**The surface herein means the outermost face of the particles, but includes the surface of the pore.**" (column 5, lines 23 to 24)

Accordingly, there is no disclosure in Yamauchi that would have motivated a person of ordinary skill in the art to modify the teachings of Boom simply by using a particulate carrier having the dimensions recited in the present claims, whereby the nucleic acids are bound to the silica of the particulate carrier. Instead, the teachings of Yamauchi would have clearly directed a person of ordinary skill in the art to carry out nucleic acid separation using a particulate carrier coated with a polyacrylamide coupling agent which binds the nucleic acid. There is no disclosure whatsoever in Yamauchi that suggests the method of nucleic acid separation recited in the claims (i.e., direct nucleic acid-silica binding). Indeed, Yamauchi clearly teaches *away* from the present invention.

Although the particle diameter, pore diameter and pore volume of the magnetic particles of Yamauchi are selected to achieve higher adsorption capacity, higher adsorption speed and higher reaction efficiency in adsorption or extraction, such dimensions are selected to obtain optimal

results by collecting nucleic acids by the interaction between nucleic acids and polyacrylamide bonded on the magnetic particle surfaces, including the pore surfaces.

In contrast, the particulate carrier used in the present invention adsorbs and collects nucleic acids by binding nucleic acid bases to hydroxyl groups on the silica particle surfaces via hydrogen bonds, and has dimensions selected to obtain optimal results by such a mechanism, i.e., a particle diameter of 0.5 to 15.0 μm, a pore diameter of 80 to 250 nm, and a pre volume of 0.2 to 5 ml/g.

Finally, Tables 1 and 2 in Yamauchi show that when using the particulate carriers of the Comparative Examples (which fall outside the scope of the present claims), which have an acrylamide content of 0 or substantially 0, the detection ratios in the nucleic acid extraction test (%) are extremely low, compared with the ratios achieved by using the acrylamide-containing particulate carriers of the Examples. These results demonstrate that, among particulate carriers with the same dimensions, those containing no acrylamide have an extremely low capability of collecting nucleic acids. This further demonstrates that persons of ordinary skill in the art would not have been motivated to combine the teachings of Boom and Yamauchi in a way that would have resulted in the present invention.

From the above, Claims 1 and 25 are obvious over Boom in view of Yamauchi. Claims 3-7, 9-22 dependent on Claim 1 are also unobvious.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection

with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 472552000100.

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Respectfully submitted,

By _____

Peter J. Davis
Registration No.: 36,119
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 300
McLean, Virginia 22102
(703) 760-7748